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9 INC. and SATURN CONSULTING LLC

10 UNITED STATES DISTRICT COURT  
11 NORTHERN DISTRICT OF CALIFORNIA  
12 SAN FRANCISCO DIVISION

13 ZELTIQ AESTHETICS, INC., a Delaware  
14 corporation,

15 Plaintiff,

16 v.

17 BTL INDUSTRIES, INC., a Delaware  
18 corporation; and SATURN CONSULTING  
19 LLC dba Monarch Laser Services

20 Defendants.

Case No.: 3:13-CV-5473-JCS

**FIRST AMENDED ANSWER TO  
COMPLAINT FOR INJUNCTIVE  
RELIEF**

1 Defendants BTL Industries, Inc. (“BTL”) and Saturn Consulting Services (“Monarch”)  
2 (collectively “Defendants”) hereby answer Plaintiff Zeltiq Aesthetics, Inc.’s (“Zeltiq”) Complaint  
3 for Injunctive Relief, as follows:

4 1. Paragraph 1 states legal conclusions to which no response is required. To the  
5 extent a response is required, Defendants deny the allegations contained in Paragraph 1.

6 2. Defendants admit that the U.S. Food and Drug Administration (“FDA”) has granted  
7 clearance to BTL to promote, market, and sell a medical device known as “Vanquish” for deep  
8 tissue heating and that the FDA clearance does not claim or reference any use to reduce fat.  
9 Except as specifically admitted, Paragraph 2 states legal conclusions to which no response is  
10 required. To the extent a response is required and except as specifically admitted herein,  
11 Defendants deny the remaining allegations contained in Paragraph 2.

12 3. Defendants lack knowledge and information sufficient to form a belief as to the  
13 allegations contained in Paragraph 3 and on that basis deny them.

14 4. Denied.

15 JURISDICTION AND VENUE

16 5. Paragraph 5 states legal conclusions to which no response is required. To the  
17 extent a response is required, Defendants deny the allegations contained in Paragraph 5.

18 6. Paragraph 6 states legal conclusions to which no response is required. To the  
19 extent a response is required, Defendants deny the allegations contained in Paragraph 6.

20 INTRADISTRICT ASSIGNMENT

21 7. Paragraph 7 states legal conclusions to which no response is required. To the  
22 extent a response is required, Defendants deny the allegations contained in Paragraph 7.

23 PARTIES

24 8. Defendants lack knowledge and information sufficient to form a belief as to the  
25 allegations contained in Paragraph 8 and on that basis deny them.

26 9. BTL admits that it is incorporated in Delaware, that it maintains its principal place  
27 of business in Framingham, Massachusetts, and that it is a privately-held company. Except as  
28

specifically admitted, Defendants deny the remaining allegations contained in Paragraph 9.

10. Admitted.

BACKGROUND

11. Defendants lack knowledge and information sufficient to form a belief as to the allegations contained in Paragraph 11 and on that basis deny them.

12. Defendants lack knowledge and information sufficient to form a belief as to the allegations contained in Paragraph 12 and on that basis deny them.

13. Defendants lack knowledge and information sufficient to form a belief as to the allegations contained in Paragraph 13 and on that basis deny them.

14. Defendants lack knowledge and information sufficient to form a belief as to the allegations contained in Paragraph 14 and on that basis deny them.

15. Defendants lack knowledge and information sufficient to form a belief as to the allegations contained in Paragraph 15 and on that basis deny them.

16. Admitted.

17. Admitted.

18. Admitted.

19. Defendants lack knowledge and information sufficient to form a belief as to the allegations contained in Paragraph 19 and on that basis deny them.

20. Defendants admit that they have stated that the FDA cleared Vanquish for applying therapeutic deep heat in body tissues. Except as specifically admitted, Defendants lack knowledge and information sufficient to form a belief as to the remaining allegations contained in Paragraph 20 and on that basis deny them.

21. Defendants admit that they have stated that the FDA cleared Vanquish for applying therapeutic deep heat in body tissues and that BTL representatives attended the April 2013 meeting of the Boston of the American Society for Lasers Medicine and Surgery, the March 2013 meeting of the American Academy of Dermatology, and the April 2013 meeting of the American Society for Aesthetic Plastic Surgery to respond to inquiries from attendees regarding Vanquish.

1 Except as specifically admitted, Defendants lack knowledge and information sufficient to form a  
2 belief as to the remaining allegations contained in Paragraph 21 and on that basis deny them.

3 22. Defendants lack knowledge and information sufficient to form a belief as to the  
4 allegations contained in Paragraph 22 and on that basis deny them.

5 23. Defendants lack knowledge and information sufficient to form a belief as to the  
6 allegations contained in Paragraph 23 and on that basis deny them.

7 24. BTL admits that it caused promotional messages to appear on the cover of the  
8 Summer 2013 issue of *New You* and that Exhibit 2 to the Complaint contains two copies of such  
9 messages. Except as specifically admitted, Defendants lack knowledge and information sufficient  
10 to form a belief as to the remaining allegations contained in Paragraph 24 and on that basis deny  
11 them.

12 25. Defendants lack knowledge and information sufficient to form a belief as to the  
13 allegations contained in Paragraph 25 and on that basis deny them.

14 26. Denied.

15 27. Denied.

16 28. Defendants admit that BTL has not received FDA clearance for a device for body  
17 contouring or fat reduction. Except as specifically admitted, Defendants deny the remaining  
18 allegations contained in Paragraph 28.

19 29. Defendants admit that the email attached as Exhibit 6 was sent on behalf of BTL.  
20 Except as specifically admitted, Defendants deny the remaining allegations contained in Paragraph  
21 29.

22 30. Denied.

23 A. Defendants admit that the website at [www.btlvanquish.com](http://www.btlvanquish.com) states, *inter*  
24 *alia*, that “[t]he Vanquish is FDA cleared for deep tissue heating.” Except  
25 as specifically admitted, Defendants deny the remaining allegations  
26 contained in Paragraph 30.A.

27 B. Defendants admit that the website at [www.btlvanquish.com](http://www.btlvanquish.com) formerly stated  
28

1 “GO TO INTERNATIONAL SITE,” that it now contains a link with the  
2 phrase “GO TO NON-US SITE,” and that access to the “international” or  
3 “non-US” site is not restricted to visitors from internet addresses outside the  
4 United States. Except as specifically admitted, Defendants deny the  
5 remaining allegations contained in Paragraph 30.B.

6 C. Defendants admit that the non-US site at  
7 [www.btlvanquish.com/en/faqs.html](http://www.btlvanquish.com/en/faqs.html) contains the statements “[t]he Vanquish  
8 is a revolutionary, non-invasive Selective RF™ system designed to deliver  
9 energy to your body to eliminate fat cells” and “[t]he Vanquish procedure  
10 was clinically tested and cleared.” Except as specifically admitted,  
11 Defendants deny the remaining allegations contained in Paragraph 30.C.

12 D. Defendants admit that the non-US site at  
13 [www.btlvanquish.com/en/Vanquish-Experience.html](http://www.btlvanquish.com/en/Vanquish-Experience.html) formerly appeared as  
14 depicted in Exhibit 9 to the Complaint and that the non-US site at  
15 [www.btlvanquish.com/en/faqs.html](http://www.btlvanquish.com/en/faqs.html) formerly appeared as depicted in  
16 Exhibit 10 to the Complaint. Except as specifically admitted, Defendants  
17 deny the remaining allegations contained in Paragraph 30.D.

18 E. Defendants admit that the non-US site at [www.btlvanquish.com/en/in-the-](http://www.btlvanquish.com/en/in-the-media.html)  
19 [media.html](http://www.btlvanquish.com/en/in-the-media.html) formerly appeared as depicted in Exhibit 11 to the Complaint.  
20 Except as specifically admitted, Defendants deny the remaining allegations  
21 contained in Paragraph 30.E.

22 F. Defendants admit that the non-US site at  
23 [www.btlvanquish.com/en/seminars.html](http://www.btlvanquish.com/en/seminars.html) formerly appeared as depicted in  
24 Exhibit 12 to the Complaint. Except as specifically admitted, Defendants  
25 deny the remaining allegations contained in Paragraph 30.F.

26 G. Defendants admit that the non-US site at [www.btlvanquish.com/en/about.us](http://www.btlvanquish.com/en/about.us)  
27 formerly appeared as depicted in Exhibit 13 to the Complaint. Except as  
28

1 specifically admitted, Defendants deny the remaining allegations contained  
2 in Paragraph 30.G.

3 31. Denied.

4 32. Defendants admit that Kevin Meyers introduced Dr. Amir Moradi to the audience  
5 at a workshop held in Los Angeles at the Westin Hotel at Los Angeles International Airport on  
6 September 29, 2013. Except as specifically admitted, Defendants deny the remaining allegations  
7 contained in Paragraph 32.

8 33. Defendants admit that Dr. Amir Moradi was the main speaker at a workshop held  
9 in Los Angeles at the Westin Hotel at Los Angeles International Airport on September 29, 2013;  
10 that Dr. Moradi relayed his experiences with both Vanquish and Exilis machines and how he had  
11 used them in his practice; and that Dr. Moradi did use before and after slides supplied by BTL  
12 depicting results achieved with Vanquish and Exilis machines. Except as specifically admitted,  
13 Defendants deny the remaining allegations contained in Paragraph 33.

14 34. Defendants lack knowledge and information sufficient to form a belief as to the  
15 allegations contained in Paragraph 34 and on that basis deny them.

16 35. Defendants admit that marketing materials for the Vanquish device can be  
17 purchased at [www.aestheticmarketingstore.com](http://www.aestheticmarketingstore.com) and that these materials include, *inter alia*, the  
18 phrases “conquer your core with Vanquish,” “banish the bulge,” “make them say . . . what ocean  
19 view?” and “don’t be cool when you can sizzle.” Except as specifically admitted, Defendants  
20 deny the remaining allegations contained in Paragraph 35.

21 36. Defendants admit that BTL and Monarch hosted a meeting in Carlsbad, California  
22 in early October 2013 and that BTL and Monarch provided copies of studies and articles to  
23 attendees after attendees requested such information and signed a written request for such  
24 information (including the materials contained in Exhibit 2 to the Complaint). Except as  
25 specifically admitted, Defendants deny the remaining allegations contained in Paragraph 36.

26 37. Defendants admit that the American Society for Dermatologic Surgery held its  
27 annual meeting in Chicago in October 2013, that BTL was a “Brass Level” sponsor of that  
28

1 meeting, that BTL invited doctors to a “private demonstration” of the Vanquish device at that  
 2 meeting, and that the invitation included the phrase “a newly FDA cleared technology . . . for non-  
 3 invasive body shaping.” Except as specifically admitted, Defendants deny the remaining  
 4 allegations contained in Paragraph 37.

#### 5 FIRST CLAIM FOR RELIEF

6 38. Defendants incorporate by reference their responses to paragraphs 1-37.

7 39. Paragraph 39 states legal conclusions to which no response is required.

8 40. Denied.

9 41. Defendants admit that the Vanquish is not FDA cleared for body sculpting or fat  
 10 reduction. Except as specifically admitted, Defendants deny the remaining allegations contained  
 11 in Paragraph 41.

12 42. Denied.

13 43. Denied.

14 44. Denied.

15 45. Defendants lack knowledge and information sufficient to form a belief as to the  
 16 allegations contained in Paragraph 45 and on that basis deny them.

17 46. Denied.

#### 18 SECOND CLAIM FOR RELIEF

19 47. Defendants incorporate by reference their responses to paragraphs 1-46.

20 48. Paragraph 48 states legal conclusions to which no response is required.

21 49. Paragraph 49 states legal conclusions to which no response is required.

22 50. Denied.

23 51. Denied.

24 52. Paragraph 52 states legal conclusions to which no response is required.

25 53. Defendants lack knowledge and information sufficient to form a belief as to the  
 26 allegations contained in Paragraph 53 and on that basis deny them.

#### 27 THIRD CLAIM FOR RELIEF

1           54.     Defendants incorporate by reference their responses to paragraphs 1-53.

2           55.     Denied.

3           56.     Denied.

4           57.     Defendants lack knowledge and information sufficient to form a belief as to the  
5 allegations contained in Paragraph 57 and on that basis deny them.

6                               FOURTH CLAIM FOR RELIEF

7           58.     Defendants incorporate by reference their responses to paragraphs 1-57.

8           59.     Paragraph 59 states legal conclusions to which no response is required.

9           60.     Denied.

10          61.     Denied.

11          62.     Denied.

12          63.     Defendants lack knowledge and information sufficient to form a belief as to the  
13 allegations contained in Paragraph 63 and on that basis deny them.

14                               AFFIRMATIVE DEFENSES

15           Defendants set forth their separate and affirmative defenses to the Complaint, without  
16 conceding that the burden of proof rests with Defendants with respect to these issues. Defendants  
17 reserve the right to assert such other separate and affirmative defenses as continuing investigation  
18 and discovery may disclose.

19           1.       Zeltiq's claims for relief are barred, in whole or in part, by the doctrines of waiver,  
20 acquiescence, and/or estoppel.

21           2.       Zeltiq's claims for relief are barred, in whole or in part, by the doctrine of unclean  
22 hands.

23           3.       Zeltiq has suffered no damages or economic harm as a result of the matters alleged  
24 in the Complaint.

25           4.       Zeltiq lacks standing to assert some or all of its claims against Defendants.

26           5.       Some or all of Zeltiq's claims are not ripe for adjudication.

27           6.       Some or all of Zeltiq's claims are moot.



7. Some or all of Zeltiq's claims for relief are barred in whole or in part because the alleged activities of Defendants are protected by the First and Fourteenth Amendments to the United States Constitution and/or by Article I, Section 2 of the California Constitution.

8. Some or all of Zeltiq’s claims for relief are preempted by the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §301 *et seq.*

## PRAYER FOR RELIEF

WHEREFORE, Defendants pray for judgment as follows:

1. That Zeltiq take nothing by its Complaint;

2. That the Court deny Zeltiq's request for injunctive relief;

3. That the Court deny Zeltiq's request for an order requiring disclosures by Defendants;

4. That the Court award Defendants' their recoverable costs and reasonable attorneys' fees as permitted by law; and

5. For such other and further relief as the Court deems just and proper.

Dated: February 4, 2013

SKAGGS FAUCETTE LLP

By: /s/  
Jeffrey E. Faucette

Attorneys for Defendants BTL INDUSTRIES, INC.  
and SATURN CONSULTING LLC